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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/500,991	02/15/2000	Frank Uhlmann	0652.2040000/REF	3282

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EXAMINER

FRONDA, CHRISTIAN L

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 10/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/500,991	Applicant(s) UHLMANN ET AL.	
	Examiner Christian L. Fronda	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 July 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36,37,40,41,43,44,46-49,58 and 59 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36,37,40,41,43,44,46-49 and 59 is/are rejected.
- 7) ☒ Claim(s) 59 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 February 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

4-D

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DETAILED ACTION

1. Claims 36, 37, 40, 41, 43, 44, 46-49, 58, and 59 are pending and under consideration in this Office Action.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 36, 37, 40, 41, 43, 44, 46-49, 58 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants' arguments filed 07/14/2005, have been fully considered but they are not persuasive. Applicants' position is that the claims include a structural and functional definition of the separin substrates having the sequence EXXR, the specification lists several separin substrates and describes methods for identifying separin substrates, and the level of skill and knowledge in the art regarding production of synthetic proteolytic substrates was extremely high at the time of filing. Applicants argue that the USPTO Written Description Guidelines and Federal Circuit's statement in *Regents of University of California v. Eli Lilly & Co. Id.*, 119 F.3d 1559,1568 (Fed. Cir. 1997) support applicants' position that the genus of separin substrates are adequately described. Furthermore, applicants argue that including claim 58 in the rejection is incorrect since there is no justification for rejecting when the human separin substrate SCC1 is disclosed in the working example of the specification. The examiner respectfully disagrees for reasons of record as supplemented below.

The claims are drawn to a method comprising the use of a genus of separin substrates, fragments, and variants thereof. The USPTO Written Description Guidelines does not support applicants' position that the genus of separin substrates are adequately described since Example 14 is directed toward a full-length enzyme of having the full amino acid sequence of SEQ ID NO:

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3 where enzymes that do not have substantial variation in amino acid sequence and structure are claimed. In contrast, the instant specification only discloses a minimal amino acid sequence of EXXR, where the separin substrates are proteins from various biological sources with widely varying amino acid sequences, structures, and biophysical properties.

Furthermore, applicants' particular citation of *Regents of University of California v. Eli Lilly & Co. Id.*, 119 F.3d 1559,1568 (Fed. Cir. 1997) does not support applicants' position that the genus of separin substrates are adequately described since a correlation between structure and function has not been well-established. While the specification states that proteins including yeast Scc1, human SCC1, *S. pombe* protein Rad21, which are known in the art have amino acid sequences comprising several hundred amino acid residues, can be used as separin substrates and that the claims as written recite minimal structure of EXXR, where X is any amino acid; the specification does not describe a substantial portion of an amino acid sequence that is common to all members of the genus of separin substrates. Thus, the skilled artisan cannot predict the structure of other species encompassed by the genus separin substrates, fragments, and variants thereof

In the evaluation of the claims for compliance with the written description requirement of 35 U.S.C. 112, of particular relevance to claims 46 and 58 are 66 FR 1099, Friday, January 5, 2001, which states:

"*Eli Lilly* explains that a chemical compound's name does not necessarily convey a written description of the named chemical compound, particularly when a genus of compounds is claimed. *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1405. The name, if it does no more than distinguish the claimed genus from all others by function, does not satisfy the written description requirement because "it does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406. Thus *Eli Lilly* identified a set of circumstances in which the words of the claim did not, without more, adequately convey to others that applicants had possession of what they claimed." (see p. 1100, 1st column, line 47 to 2nd column, line 2).

Claims 46 and 58 are drawn to a method comprising the use of human SCC1, fragments, and variants thereof. Those substrates that are "human" are a subgenus of the genus of separin substrates. The scope of the subgenus includes many members with widely differing structural, chemical, and physiochemical properties including widely differing amino acid sequences. Furthermore, the subgenus is highly variable because a significant number of structural differences

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between genus members exists.

While the specification discloses a peptide derived from human SCC1 substrate and consisting of SEQ ID NO: 1; the recitation of the name "human SCC1" does not define any structural features and amino acid sequences commonly possessed by the genus. Furthermore, the specification does not describe and define any structural features and amino acid sequences commonly possessed by the subgenus of separin substrates. Thus, one skilled in the art cannot visualize or recognize the identity of the members of each genus for use in the claimed method. In view of these considerations, one of skill in the art would not recognize that applicants were in possession of human SCC1, fragments, and variants thereof.

Claim Rejections - 35 U.S.C. § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 36, 37, 40, 41, 43, 44, and 48 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Brown et al. (reference AJ cited in PTO 1449 dated 08/03/2000) in view of Ciosk et al. (reference AM cited in PTO 1449 dated 08/03/2000).

Applicants' arguments filed 07/14/2005, have been fully considered but they are not persuasive. Applicants' position is that there is no evidence for motivating a person of ordinary skill in the art to modify or combine Brown et al. and/or Ciosk et al. and that not all of the elements of the claims are taught or suggested by Brown et al. and/or Ciosk et al.

The specification states the following regarding Esp1p as taught by Ciosk et al. (1998) on page 4, lines 3-11:

"Both the dissociation of Scc1p from chromosomes and the separation of sister chromatids are dependent on a **specialized sister separating protein (a separin) called Esp1p (Ciosk et al., 1998)**. Separins homologous to Esp1 exist in the fission yeast *Schizosaccharomyces pombe*, in the fungus *Aspergillus nidulans*, in the nematode worm *Caenorhabditis elegans*, the

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fruit fly *Drosophila melanogaster*, in the frog *Xenopus laevis*, in the plant *Arabidopsis thaliana*, and in man. This strongly suggests that separins have a fundamental role in chromosome segregation that is conserved between plants, fungi, and animals.” (emphasis added).

On page 36, line 21, the specification states the following regarding Scc1: “Purified yeast Scc1 is a substrate for Esp1-dependent cleavage.”

Thus, the examiner takes the position that the Esp1p taught by Ciosk et al. inherently is a separin and the yeast substrate Scc1 disclosed by Ciosk et al. inherently is a substrate for the taught Esp1p.

One of ordinary skill in the art at the time the invention was made would have been motivated to modify the teachings of Brown et al. such that the separin and yeast substrate Scc1 taught by Ciosk et al. is used in the process taught by Brown et al., where the yeast substrate Scc1 is labeled at one end with a UV/blue fluorophore and at the other end a quencher, for the purposes of having a fast and simple process for assaying and identifying separase inhibitors.

Because no patentable weight is given to the preamble of process claims 36, 37, 40, 41, 43, 44, and 48 since it merely recites the purpose of these process claims, then the modified Brown et al. process which recites the limitations of the process steps would inherently identify compounds that inhibit sister chromatid separation in eukaryotic cells.

The examiner has determined the scope and contents of the prior art references of Brown et al. and Ciosk et al., ascertained the differences between the prior art and the claims at issue, and found the claimed invention to have been obvious in light of the combined teachings of the references.

Conclusion

6. No claims are allowed.

7. Claim 59 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Friday between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

10. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CLF


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